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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,789	07/26/2001	Lieping Chen	07039-219001	6835

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,789	Applicant(s) CHEN, LIEPING	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendment, filed 1/16/02, is acknowledged.
Claims 1-52 are pending.

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Drawing Requirement

3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

Restriction Requirement

4. Prior to setting forth the restriction requirement, it is noted that claims depending from claims 10 and 41 encompass methods of co-stimulating a T cell that utilize different method steps to contact the T cell with the polypeptide: administering a polypeptide directly, administering a nucleic acid that encodes the polypeptide; and administering a cell modified to express the polypeptide. These methods utilize different products (the polypeptide per se, DNA, or a transfected cell) in these different method steps, and each requires a different search. In addition, these methods are classified in different classes and/or subclasses, as set forth below.

The restriction has therefore been set forth for these methods as separate groups, irrespective of the format of the claims.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, 7-9 and 32-33, drawn to DNA sequences related to SEQ ID NO:6 or a DNA encoding SEQ ID NO:5; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

II. Claims 4-6, drawn to a polypeptide related to SEQ ID NO:5; classified in Class 530, subclass 395.

III. Claims 10-13, 19 and 52, drawn to a method of co-stimulating a T cell by contacting the T cell *directly with a polypeptide* encoded by SEQ ID NO:6, classified in Class 424, subclass 184.1.

IV. Claims 10, 12, 14, 19 and 52, drawn to a method of co-stimulating a T cell by contacting the T cell with a polypeptide *expressed from an administered nucleic acid* related to SEQ ID NO:6, classified in Class 514, subclass 44.

V. Claims 10, 12, 15-19 and 52, drawn to a method of co-stimulating a T cell by contacting the T cell *with a recombinant cell* transfected with a nucleic acid encoding a polypeptide related to SEQ ID NO:5, classified in Class 424, subclass 93.21.

VI. Claims 20-23, drawn to a method of identifying a compound that *inhibits* an immune response, classified in Class 435, subclass 4.

VII. Claims 24-27, drawn to a method of identifying a compound that *enhances* an immune response, classified in Class 435, subclass 4.

VIII. Claims 28-31, drawn to an antibody that binds the polypeptide of SEQ ID NO:5 or a related polypeptide; classified in Class 530, subclass 387.1.

IX. Claims 34-35, drawn to a fusion protein comprising the polypeptide of SEQ ID NO:5 or a related polypeptide; classified in Class 530, subclasses 350 and 387.3.

X. Claims 36-40, drawn to a nucleic acid molecule encoding a fusion protein comprising the polypeptide of SEQ ID NO:5 or a related polypeptide; vectors, host cells, and methods of producing the fusion protein, classified in Class 536, subclass 23.4 and Class 435, subclasses 69.1, 455, 252.3, and 320.1.

XI. Claims 41-44 and 51, drawn to a method of co-stimulating a T cell by contacting the T cell *directly with* a first co-stimulatory polypeptide and one or more additional co-stimulatory polypeptides, classified in Class 424, subclass 184.1.

XII. Claims 41 and 43, drawn to a method of co-stimulating a T cell by contacting the T cell with a first co-stimulatory polypeptide and one or more additional co-stimulatory polypeptides *expressed from administered nucleic acids*, classified in Class 514, subclass 44.

XIII. Claims 41, 43, 46 and 48-51, drawn to a method of co-stimulating a T cell by contacting the T cell *with a single recombinant cell* transfected with nucleic acids encoding a first co-stimulatory polypeptide and one or more additional co-stimulatory polypeptides, classified in Class 424, subclass 93.21.

XIV. Claims 41, 43, 47 and 51, drawn to a method of co-stimulating a T cell by contacting the T cell *with a recombinant cell* transfected with a nucleic acid encoding a first co-stimulatory polypeptide and *with a recombinant cell* transfected with a nucleic acid encoding one or more additional co-stimulatory polypeptides, classified in Class 424, subclass 93.21.

The Inventions are distinct, each from the other because:

6. Groups I, II, VIII, IX and X are different products. Nucleic acids, polypeptides, antibodies to the polypeptides and fusion proteins differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

7. Groups (I and II) and (X and IX) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the protein product can be made using an amino acid synthesizer and in addition the fusion protein can be made by chemical linkage.

8. Groups III, IV, V, VI, VII and XI-XIV are different methods. As noted supra, each method of co-stimulating, as well as the methods of identifying, each differs with respect to one or more of ingredients, method steps, or endpoints; therefore, each method is patentably distinct.

9. Groups (I and IV/V/XII/XIII/XIV) and (II and III/VI/VII/XI) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case:
the nucleic acid of Group I can also be used in a method of producing protein; the polypeptides of Group II can be used to produce antibodies; and the antibody of Group VIII can be used for affinity purification.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed Inventions V and XIII: wherein the recombinant cell is:

A) an APC not pulsed with antigen,
B) an APC pulsed with antigen or an antigenic peptide, or
C) a tumor cell.

These species are distinct because each recombinant cell differs in physiological properties; thus each method employing these distinct cells represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15 and 46 are generic.

12. This application contains claims directed to the following patentably distinct species of the claimed Inventions VI and VII: wherein the T cell activating stimulus is:

A) an antibody to TcR,
B) an antibody to CD3,
C) an alloantigen, or
D) an antigenic peptide.

These species are distinct because each stimulus differs in structure and mode of action; thus each method employing these distinct stimuli represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20 and 24 are generic.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
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September 19, 2002

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